

TUBERCULOSIS CONTROL

as an
integral part
of primary health
care



WORLD HEALTH ORGANIZATION
GENEVA

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Tuberculosis Control as an Integral Part of Primary Health Care

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Preface

A tuberculosis programme that is to meet legitimate social demands and have a progressive epidemiological impact must be countrywide and permanent. In developing countries these requirements can be met only when the programme is integrated within the general health services. But while the principle of integration has been readily accepted, its application has encountered many practical problems.

New opportunities for tuberculosis control, but also new problems, arose with the adoption of the concept of primary health care: on the one hand it greatly enlarged the scope for extending tuberculosis control to the whole population; on the other hand it posed additional practical problems with respect to such programme components as planning, training, provision of supplies, and supervision.

To review the practicability of tuberculosis control technology at the different primary health care levels and to advise on technical as well as operational problems in the integration process, a consultation was held by the World Health Organization in Geneva from 22 to 26 September 1986. The meeting brought together experts in tuberculosis and in primary health care.

Although the experts obviously could not produce a universal blueprint for the integration of tuberculosis control, they tackled the key issues and proposed many solutions in the true spirit of primary health care. The ideas they raised, which are reproduced in this book, deserve careful study by all organizers of primary health care programmes and administrators of national tuberculosis programmes.

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Emeritus Regional Director for Europe

1. The concept of tuberculosis control as an integral part of the health services

Almost all developing countries attempting to provide health services for their population have had to rely on limited resources, including funds, facilities and trained personnel, to cope with a vast unmet demand for health care for a variety of serious health problems. A typical response to this dilemma was the establishment—often with external urging and assistance—of special programmes aimed at specific diseases or conditions. The selection of health problems to be tackled and methods to be used was often strongly influenced by external donors and indigenous doctors with specialized interests. Thus, there came into being in many countries a set of vertical single-purpose programmes each with a virtually independent infrastructure responsible for its planning, staffing, supplies and evaluation. These programmes competed with each other, as well as with any existing system catering to the treatment of common illnesses, for scarce local and external resources. All failed to satisfy the needs of the population as a whole, often even in the short term.

Recognition that this fragmented approach was both wasteful of resources and relatively unproductive (the smallpox eradication programme being a noteworthy exception) came gradually and at a different pace in each country.

When WHO and UNICEF convened the International Conference on Primary Health Care at Alma-Ata, USSR, in 1978,¹ commitments to equity and justice in health services

¹ *Alma-Ata 1978. Primary health care.* Geneva, World Health Organization, 1978 ("Health for All" Series, No. 1).

were gaining hold in many countries. Efforts to implement integrated approaches to health care had already begun. Indeed, proclamation of the goal of Health for All by the Year 2000 was a logical outgrowth of these earlier developments.

One such development was the concept of a comprehensive tuberculosis control programme implemented on a country-wide scale through the network of existing health services. This concept was formulated in the early 1960s, in the Eighth Report of the WHO Expert Committee on Tuberculosis,¹ and reaffirmed in the Ninth Report in 1974.² The main principles were that a tuberculosis programme should be:

- countrywide, because tuberculosis is usually fairly evenly distributed; for both epidemiological and social reasons the programme should attain a high population coverage from the start;
- permanent, because cases will continue to develop from the large pool of individuals already infected;
- adapted to the expressed demands of the population so as to be both acceptable and accessible to them.

In many developing countries progress in establishing integrated tuberculosis control activities has been very slow. Since tuberculosis continues to attack millions of people every year, particularly in the less developed countries, new, imaginative approaches are badly needed.

Fortunately, progress in implementing primary health care has created circumstances that are favourable to the development of integrated tuberculosis control programmes. In the past, recommendations for tuberculosis control policies

¹ WHO Technical Report Series, No. 290, 1964 (*Tuberculosis: eighth report of the WHO Expert Committee*).

² WHO Technical Report Series, No. 552, 1974 (*Tuberculosis: ninth report of the WHO Expert Committee*).

and strategies were formulated mainly by groups of tuberculosis specialists. Although these experts invariably recognized the need for integration, they were unable to provide precise guidelines on how to achieve it. Today it is possible to prepare realistic action plans through collaboration between tuberculosis specialists and primary health care organizers.

The primary health care approach, as embodied in the Declaration of Alma-Ata, recognizes the basic right to health for each individual and rests on the principle of equitable use of health resources, especially with regard to the coverage and effectiveness of health care. Its basic requirements are:

- that there should be total coverage of the population with basic but essential health care, particular attention being given to needy, vulnerable groups;
- that services should focus on the major health problems of the population, should be affordable, and should employ technologies that are locally appropriate as well as acceptable;
- that communities should participate actively in the planning, implementation and evaluation of health services; and
- that health services should coordinate with other sectors involved in development, since progress in health leads to, and at the same time depends on, socioeconomic progress.

Integrating tuberculosis control into a health care system of this kind was initially expected to be an easy task, given the availability of a relatively simple technology, capable of gradual implementation, that could seemingly be applied in almost any setting. Since then it has been realized that good health management is as critical for success as sound health technology, and that managerial skills merit increasing priority in developing countries. Managerial weaknesses have become particularly evident at the intermediate or district levels where, as countries expand their health

services, decision-making and support structures must be built up. It is now obvious that the primary health care approach cannot rely on central planning and management alone. As will be seen later, district-level health planning and management is needed to deal rationally with the organizational requirements of these geographically defined areas.

2. The tuberculosis problem: magnitude and trends

About a million new cases of tuberculosis are officially reported by ministries of health each year, and fewer than 200 000 deaths. These figures greatly underestimate the magnitude of the problem because tuberculosis is now largely concentrated in the developing world, where the means of detecting, diagnosing and reporting the disease are grossly deficient.

Estimates of the true size of the problem are derived from surveys. The incidence or risk of infection is the best indicator. In the absence of bovine infection, the only transmitters of the disease are tuberculosis patients who discharge tubercle bacilli. Thus the incidence of infection reflects to some extent the number of sources of infection in the population. The annual risk of infection can be determined through tuberculin surveys of representative population samples. Although it is difficult to obtain precise prevalence data in countries where BCG vaccination has been extensively practised or where infection with environmental mycobacteria is common, it can be estimated from repeated surveys that in most developing countries from 1% to 4% of the population is newly infected (or reinfected) each year.

The incidence of new infections defines the magnitude of the problem but it is profitably accompanied by an estimate of the trend in past years. Before the 1940s, the risk of infection in northern Europe typically decreased by 3.5–5.5% per year—the so-called “natural decline” in an industrialized society. After the introduction of chemotherapy, the annual decline accelerated to 10.5–14.5%. In the developing countries, both the prevalence and the risk of infection are still high, case-finding is inadequate, case-

holding is often very poor, and coverage of the population is very incomplete. Nevertheless, tuberculin re-surveys in recent years have almost invariably shown significant declines in the risk of infection. The annual decline has been between 5% and 10% in many Latin American, Arab and Western Pacific countries, 6–7% in areas of large Asian countries, and 2–4% in some African countries. This progress could no doubt be hastened by extending tuberculosis control programmes and improving their quality.

There appears to be a constant ratio between the annual risk of tuberculous infection and the annual incidence of sputum smear-positive cases, with every 1% of infection corresponding to 50–60 new smear-positive cases of pulmonary tuberculosis per 100 000 population. Furthermore, for every case of smear-positive pulmonary tuberculosis there is usually at least one case of smear-negative pulmonary tuberculosis or extrapulmonary disease. On this basis it is estimated that in the Third World there are each year 4–5 million new smear-positive cases and another 4–5 million smear-negative and extrapulmonary cases. Prevalence is two to three times higher.

In the developed countries, morbidity declines at a significantly slower pace than the risk of infection because the incidence of new cases depends mostly on endogenous reactivation of old infections. The situation is quite different in the developing countries, where the risk of infection remains high. Here, exogenous (re)infection is important, and the decrease in incidence, in young people, nearly corresponds to the decrease in the risk of infection.

Recent circumstances, especially in Africa, are bound to worsen tuberculosis morbidity, reducing or even cancelling any benefits already gained. Widespread undernutrition, or even famine, and the spread of the human immunodeficiency virus (HIV) responsible for AIDS are likely to result in a higher incidence of clinical disease among the infected population.

In the present chemotherapy era, mortality is less an epidemiological index than an indicator of the efficiency of case management. However, no epidemiological analysis can afford to ignore it. Since the number of both untreated and defaulting patients is very large, there are still 2–3 million tuberculosis deaths annually in the world.

3. BCG vaccination and chemo-prophylaxis

Introduced as an emergency measure at a time when no other tuberculosis control activity was feasible, mass BCG vaccination has been replaced by BCG vaccination of the newborn within the global expanded programme on immunization. However, BCG vaccination of risk groups and of schoolchildren is still carried out in many developed countries.

It is in the interest of every tuberculosis control programme to support the expanded programme on immunization within primary health care by facilitating neonatal and infant vaccination in all ways possible. Vaccination against childhood tuberculosis is highly effective only when a potent vaccine is properly administered.

Revaccination, without tuberculin testing, is performed at school age in many countries, but there is no scientific evidence that revaccination at this age is useful in tropical areas. Policies in individual countries should be determined by the national-level tuberculosis control programme in accordance with the epidemiology of the disease and of environmental mycobacterial infection in the country.

BCG vaccination of high-risk adults as a general policy is controversial, but in some countries it is carried out in hospital and laboratory workers who are tuberculin negative; its use in other groups such as military recruits may be considered.

The tuberculosis control programme at national level should be responsible for evaluating the effectiveness of BCG vaccine, whether locally produced or procured from abroad,

and for providing advice and guidance on BCG vaccination to the expanded programme on immunization and the primary health care programme.

Household contacts of smear-positive cases are at very high risk of infection and disease, especially young children. Because of delays in the detection of smear-positive cases, many of these contacts have been infected by the time the index case is diagnosed. To reduce the problem of childhood tuberculosis, isoniazid could be administered prophylactically to all children under 5 years old who live in the household of an index case. This would be medically reasonable because the protective effect of chemoprophylaxis is greatest in children, the toxic effect in children is low, and isoniazid alone is an effective therapy in most children with primary pulmonary tuberculosis. The procedure may be logistically and economically feasible because the supervision of therapy among children in a household already containing a supervised index case will not add intolerably to the burden of health personnel and because isoniazid is the least costly drug in the armamentarium. Nevertheless, the introduction of a policy of chemoprophylaxis of children should not receive priority until a high level of success is being achieved in the treatment of smear-positive index cases. At the time of diagnosis of the index case, older contacts should be questioned for symptoms and have their sputum examined and, if indicated, be brought under appropriate chemotherapy.

Mass chemoprophylaxis of asymptomatic tuberculin-positive individuals is unrealistic. It would be very expensive and carry an appreciable risk of serious toxicity, in particular isoniazid hepatotoxicity, for the large proportion of individuals who would not benefit from the measure.

4. Case-finding and treatment

Case-finding and treatment are closely linked and are best considered as one programme activity. This is the activity that must have the highest priority in the entire tuberculosis control programme. Like BCG vaccination and chemoprophylaxis, case-finding and treatment have the social objective of preventing suffering and premature death and the epidemiological objective of interrupting transmission (by rendering patients non-infectious) and thus reducing the tuberculosis burden in the future.

Sputum smear-positive cases are the principal source from which new infections originate, which is why they must be treated promptly. Persistently smear-negative but culture-positive cases are less infectious. A major question, especially as regards the epidemiological objective, is whether it is feasible and rewarding to detect and treat cases before they become smear-positive.

The first priority is to establish passive case-finding facilities, i.e., conveniently located centres where persons with symptoms can have an adequate diagnostic test. Smear microscopy has been shown to be sufficiently sensitive to detect a large proportion of the patients among persons who actually present with symptoms that suggest the possibility of tuberculosis to the staff.

Passive case-finding requires alert and motivated health personnel; many patients fail to be diagnosed because tuberculosis is not considered, or because the skilled examination of sputum smears is delayed or not performed at all despite patients' repeated attendance at clinics because of their symptoms. But it also requires awareness and motivation

among the public. Its effectiveness can, therefore, be improved by the triple strategy of increasing programme accessibility (convenient location, ready availability of diagnostic and treatment facilities), improving its acceptability (rapid and sympathetic patient handling), and educating the public.

Intensification of case-finding through community networks, such as village health volunteers or community leaders, may be very productive. It should become a part of the countrywide programme as soon as a high level of success is achieved in curing the patients who present themselves for diagnosis and are found to require treatment.

Patients who have suggestive symptoms but are persistently sputum smear-negative on microscopy are a problem group. Whenever possible these cases should be referred for X-ray examination. If lesions are found on X-ray, sputum culture should if possible be undertaken. Culture is far more sensitive than smear microscopy; it usually detects a considerably higher proportion of patients among persons with symptoms. Culture is also far more specific than smear microscopy, and is indicated for patients who show only scanty positive smears, so as to avoid overdiagnosis (false-positives). Its availability may be essential for the transition from passive to active case-finding. This applies particularly if screening by radiographic examination is being considered for selected high-risk groups.

Active case-finding by repeated mass X-ray examination of large population segments is expensive and unproductive in developed countries. For developing countries it cannot be considered. However, efforts directed to carefully targeted high-risk groups may be useful and should be considered once the permanent case-finding activities mentioned above and highly effective case-holding have become established, and a very high cure rate is being achieved.

Childhood tuberculosis cannot be discovered by passive case-finding based on sputum smear examination except in a

small proportion of cases. Child contacts of smear-positive adult cases should be examined clinically and if possible by X-ray. They should be followed up as a high-risk group for the development of clinically evident disease.

When childhood tuberculosis is diagnosed, the patients should be treated with drug regimens shown to be highly effective in adults, although direct bacteriological confirmation of cure will not be possible except in a small minority of children.

Special population groups, such as contacts of smear-positive cases, nomads, refugees from natural and man-made disasters, immigrants from high-prevalence areas to low-prevalence areas, homeless persons, alcoholics and other drug abusers, AIDS patients and HIV-infected persons, represent definable and often readily identifiable high-risk groups for tuberculosis, and therefore may be given special attention on both humanitarian and epidemiological grounds. If logistically feasible, active case-finding should be undertaken with the help of health personnel, the community network, and special facilities such as food distribution centres. Adults with a clinical diagnosis only should not be treated, but those with X-ray changes and chest symptoms suggestive of active tuberculosis (particularly smear-negative contacts of a smear-positive index case) and children diagnosed clinically or radiologically as having childhood tuberculosis should be given treatment for the disease.

5. Organization of sputum smear examination

Sputum smear examination is a critical element of tuberculosis control programmes in developing countries, where smear-positivity is the essential component of the operational definition of a "case". Effective smear examination requires skill in collecting adequate specimens and technical expertise in selecting the most appropriate portion for examination, preparing adequate smears, staining them correctly and examining them skilfully by microscopy. In addition, careful and methodical record-keeping and reporting are vital. A single negative smear does not necessarily mean the absence of bacillary excretion; excretion may be intermittent or scanty. At least a second (preferably "overnight") specimen should be collected and examined. Conversely, if facilities permit, a positive finding—particularly if scanty—should be confirmed by the examination of a second specimen.

Ideally, sputum collection and examination should take place as close as possible to the patient in order to facilitate attendance and to obtain a quick report. These advantages must, however, be balanced against the greater efficiency and skill that are likely to be found in referral examination centres. In general, a specialized microscopy centre should serve a larger population than the laboratory of a multi-purpose centre.

Smear examiners, whether full-time or part-time technicians, require training, refresher training, supervision and motivation. Training must be given by teachers who are themselves skilled, must be practical, and must cover the whole range of the examination process. Supervision is by direct observation and entails checking technical performance by re-examination of all positive and a sample of the negative

slides at a reference laboratory, and by a comparison of actual output with estimates (quotas) of numbers of slides to be examined per unit of population and percentages of positive slides. Motivation is likely to be improved if microscopists can be convinced of the importance of their role, if their supervisors are persuasive, if work well done is praised and criticism for poor work is constructively conveyed. Some ongoing review of workloads must be made, as well as of efficiency.

The prompt identification of smear-positive cases is as important as the detection of a large proportion of such cases. An indirect indicator of delay on the part of the patient or the health service is the percentage of patients who die of tuberculosis within a few weeks after they are found. A large percentage of patients detected after self-referral, at a higher-level facility, points to poor service and delay at the lower level.

The ideal procedure is the examination of three sputum specimens collected on separate occasions (early morning, preferably) before a patient is declared to be smear negative. This ideal must be balanced in practice against the total workload.

The intensification of active case-finding—for example, through the use of community volunteers—will increase the number of suspects to be examined by sputum smear examination. This is theoretically desirable, but it must be recognized that as the number of such suspect cases increases the proportion of positive smears will probably decrease. Intensified case-finding thus yields diminishing returns and calls for a realistic appraisal of laboratory capacity and the justifiability of hiring extra microscopy staff.

Detecting positive smears is useless unless the patients can be brought under therapy. Accurate identifying data and addresses must be recorded for all patients, because every effort must be made to contact them and bring them under treatment.

It is highly desirable to have at least one reference laboratory in each country capable of culturing and identifying *Mycobacterium tuberculosis*. Apart from expanding case-detection (e.g., by culturing sputum from X-ray suspects), culture can be used to follow the course of therapy and so establish the success or failure of treatment. It is valuable for epidemiological monitoring of the prevalence of resistant strains. Such epidemiological uses should be given a very high priority. A national reference laboratory also has an important role in training, supervision and quality control of all laboratory techniques and of staff.

6. Chemotherapeutic regimens

The Ninth Report of the WHO Expert Committee on Tuberculosis emphasized “the importance of giving adequate chemotherapy to every patient with infectious pulmonary tuberculosis”. It stressed that “modern chemotherapy should cure almost all newly diagnosed patients if an effective regimen is provided for an adequate period of time and if regular ingestion of the drugs by the patient is secured”, the early stages of chemotherapy being crucial for the final outcome of treatment. It also noted that in selecting the regimens to be used, national programmes must give due weight to the efficacy, toxicity, acceptability, bulk, and cost of the available drug combinations, the capacity to supervise intermittent regimens, the feasibility of giving drugs by injection, and other local considerations.

Although many drug regimens have been carefully assessed in properly conducted controlled clinical trials, no general recommendation for one outstanding, universally applicable regimen can be made. A national programme is likely to select more than one regimen and should clearly specify the circumstances and conditions under which each should be used. For example, regimens for urban and rural patients may well differ. An important consideration is the level of success aimed for.

It is important to assure the long-term supply of all the drugs required for the selected regimens. Drugs should always be free of charge to the patient. Combinations of drugs in one tablet, e.g., isoniazid with rifampicin, ensure that both or neither are taken by the patient. Such well-established combinations should be used whenever possible.

Short-course versus long-course regimens

Currently recommended long-course regimens are of 12 months' duration at least and are of two types. One type

has an initial phase (up to 3 months) of daily administration under full supervision¹ of three drugs, which include both isoniazid and streptomycin, followed by a phase of daily self-administration of two drugs (isoniazid and thioacetazone or isoniazid and ethambutol). The other regimen consists of twice-weekly fully supervised administration of two drugs (isoniazid and streptomycin) throughout. For self-administered regimens the oral supplies are usually dispensed at intervals varying from weekly to monthly.

Most short-course regimens have a 2-month initial phase, always with isoniazid and rifampicin and usually pyrazinamide given daily or intermittently under full supervision, followed by a daily or intermittent continuation phase always including isoniazid and, whenever possible, rifampicin. If rifampicin is given throughout and pyrazinamide in the first 2 months, a total duration of 6 months is highly effective. However, if rifampicin is given only for the first 2 months and, for example, isoniazid is given with thioacetazone in the continuation phase, a total duration of 8 or 9 months is desirable.

Both long- and short-course regimens can cure over 90% of patients, with a small percentage of relapses, provided that the control programme is well organized and, above all, that patient compliance is good.

There is little to gain therapeutically from prolonging long-course regimens beyond 12 months as this has little influence on the relapse rate. Further, patients on such protracted regimens are often non-compliant.

All regimens require very high standards of supervision to ensure patient compliance and to avoid the diversion of rifampicin to the treatment of other infectious diseases.

¹ "Full supervision", as it applies to tuberculosis chemotherapy, means that drugs are administered directly to the patient by a health worker or are taken in the presence of a health worker.

Short-course regimens more quickly produce sterilization of pulmonary tuberculosis lesions. Therefore, they are more likely to lead in practice to cure, even in patients who default in substantially less than 6 months. Because of their shorter duration, such regimens tend to have fewer defaulters than long-course regimens.

Short-course regimens have been declining in cost, although in most countries they are still considerably more expensive than long-course regimens. However, the shorter duration of case-holding and the higher chance of success leads overall to lower programme costs. Tuberculosis control programmes wishing to make the transition from long-course to short-course regimens will need to do careful planning in order to avoid temporary confusion, drug supply problems, and disruption of records.

Continuous versus intermittent regimens

Some regimens, particularly short-course ones, include as alternative options the daily administration of drugs or the intermittent administration of the same drugs, i.e., two or three times per week. A number of regimens that are intermittent throughout or in the continuation phase have been shown to be as effective as daily regimens, and are less costly because the total amount of drugs needed to achieve a cure is greatly reduced.

Intermittent regimens make it easier to organize full supervision of chemotherapy. Such supervision may become an important role for primary health workers.

Hospitalization versus ambulatory treatment

Routine hospitalization of tuberculous patients, once standard management in developed countries, has been to a

great extent replaced by ambulatory treatment following the demonstration of the high potency of chemotherapeutic drugs in ambulatory patients. The Ninth Report of the WHO Expert Committee recommended that "the financial resources and manpower available for tuberculosis control be used to organize efficient and widespread ambulatory programmes rather than to support hospital treatment".

Routine hospitalization of tuberculous patients should not be a part of control programme operations. It prevents patients from leading a socially active life and creates practical and economic problems for them and their families, as well as for the control programme. The invariably limited inpatient capacity may hinder the expansion of case-finding activities. Nevertheless, if their clinical status requires it, tuberculosis patients should be admitted to hospital. They should be discharged as soon as they have improved sufficiently to continue treatment as outpatients.

The need for supervision of chemotherapy does not in itself justify hospitalization. Supervised ambulatory chemotherapy should be organized as the first priority in national tuberculosis programmes. It is important to explore a variety of operational methods to achieve adequate supervision, above all including use of the primary health care structure, when it exists. If the patient's home is so far from the health service or so inaccessible that supervision of treatment is impossible, and if facilities for hospitalization are available, then it is justified to admit patients for the initial intensive phase of treatment. No special wards for tuberculosis patients are necessary, although their beds should be located in a specific area to simplify their management, including the full supervision of chemotherapy.

Bacteriological failure and relapse

Bacteriological failure (deterioration during chemotherapy or continued bacterial positivity at the end of the course)

and bacteriological relapse (the reappearance of bacteria in the sputum after completion of a course of treatment) should occur only infrequently with effective chemotherapy regimens in well organized control programmes.

With the use of modern drug combinations in short-course regimens, provided that therapy is uninterrupted, the cure rates of patients infected with initially resistant strains (that is, strains resistant to one or more drugs before therapy is initiated) are nearly as good as the cure rates in patients with fully sensitive strains. Further, acquired resistance (the emergence of bacterial resistance during therapy) is very uncommon under such conditions. If bacteriological failure and relapse occur in more than a small percentage of patients, this usually suggests irregular drug-taking. It may also occur in patients with impaired immune defences, such as those infected with HIV. Ideally, culture examination is undertaken to confirm persistent bacterial negativity. If, as is usually the case in developing countries, culture facilities are not available, the outcome of treatment is assessed by sputum smear examination. However, a single positive result among a series of negative findings should be interpreted with caution, as should scanty positive smears. In the event of bacteriological failure during correct therapy, further treatment—if possible with a potent second-line regimen—is the aim. In the event of bacteriological relapse, retreatment with the same first-line drug combination can be prescribed for a longer period of time, especially if it was one of the short-course chemotherapy regimens.

Routine sensitivity testing in newly discovered cases is unnecessary. However, if adequate culture facilities exist, a random sample of cultures from new cases should be investigated from time to time to assess the level of initial drug resistance in the community. Sensitivity tests should be undertaken in laboratories of a proven high standard and, when possible, in cooperation with an international reference laboratory.

7. Integration of tuberculosis control into primary health care

Structure and management

The persisting high prevalence and high risk of infection in developing countries, where tuberculosis continues to claim millions of victims every year, make it vital to improve case-finding and case-holding and to extend these measures to entire populations. Integration of tuberculosis control activities within primary health care offers new opportunities for doing just this. By improving the diagnostic and case-management skills of health workers based at peripheral health units, it should be possible to maximize the impact of tuberculosis control measures. This applies to case detection in communities, confirmation of diagnosis and management of chemotherapy, as well as to education of the general public. Clearly, the efforts directed to tuberculosis control must reflect the comparative severity of the disease and take into consideration the means available for its control in relation to other health problems.

In order to maintain high standards of care by health workers as well as to provide them with the required diagnostic equipment and drugs, a well organized support system is indispensable. In vertical programmes, support for activities at the community level usually could be provided centrally, although the actual support system often needed to be so extensive that the programme faced the dilemma of either absorbing an inordinate portion of available resources or else failing in the coverage of the population. Integrated programmes call for a different approach. Whereas centrally, or even regionally, a certain vertical structure of specialized programme components remains justifiable,

effective integration should be achieved somewhere at the intermediate level so that balanced support can be provided to the community programme. This view has led to the concept of the *district health programme*.

In this concept, the district is a geographical area that is small enough for its health and related social and economic problems to be properly understood and for appropriate action to be taken in response, but large enough to permit the deployment of essential technical and managerial skills for planning and management of the health programme. If these conditions are met, the health programme will be not only manageable but also more finely adjustable to the actual needs of the population.

A district health system based on primary health care is a more or less self-contained segment of the national health system. It covers a well-defined population living within a clearly delineated administrative and geographical area, whether urban, rural or both. It includes all institutions and individuals providing health care in the district, whether governmental, social security, nongovernmental, private or traditional. A district health system therefore consists of a large variety of inter-related elements that contribute to health in homes, schools, workplaces and communities, through the health and other related sectors. It includes self-care and all health care workers and facilities, up to and including the hospital at the first referral level, and the appropriate laboratory, other diagnostic, and logistic support services.

In the past it was often thought that strong vertical programmes could be the "entry-point" for the development of a health system. Experience has shown that this is not the case. Vertical programmes create their own constituencies, consisting of their own staff. They resist integration and the "dilution" of their missions, and compete for the inevitably limited resources. Therefore, if integrated tuberculosis control has to be developed almost from scratch, it is best to avoid creating a vertical

programme; instead, the resources should be devoted to strengthening the general primary care infrastructure. This may be done by gradually providing the essential elements of primary health care¹ in keeping with local needs. If other vertical programmes exist, e.g., for the control of leprosy, yaws, malaria, trachoma, or for family planning, their relevance to local needs and priorities should be assessed. Activities that fit in with local priorities should continue. If important problems are not being tackled, resources must be re-allocated.

Skilled management of the integration process implies:

- *information* based on a detailed situation analysis of the existing position;
- *planning* the integration process;
- *delegation* of authority and responsibility, so as to enable managers at lower levels in the hierarchy of the programme structure to participate in planning at their respective levels;
- *training and motivating* staff at all levels to carry out their new functions and activities;
- *supervision* of the implementation of the integration schedule; and
- *evaluation*, i.e., analysis of the impact of integration on programme operations and patient care.

Planning involves more than preparing a general statement of overall objectives. It requires a detailed consideration of specific activities and who does what, how, with what training and supervision, and with what support. Planning for

¹ The Declaration of Alma-Ata specifies that primary health care must include at least the following eight elements: education concerning prevailing health problems and the methods of preventing and controlling them; promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs.

the integration of tuberculosis control into the district infrastructure is no exception. Detailed plans need to be prepared setting out the operational steps involved, specifying the timetable for their completion, and designating the personnel responsible for each of the tasks. Every district in every country must do this type of planning for itself, adapted to national guidelines and local realities. The district plan should focus on service delivery as well as supportive activities. Any programme support, such as training, supplies and surveillance, that needs to be provided by levels above the district should then be organized in the light of the district plan.

Motivation of programme workers is an especially difficult managerial challenge. If they are transferred into a primary health care programme that they recognize to be weaker and less specifically targeted than the vertical programme that is discontinued, they may resent giving up their old activities and taking on a variety of new ones. Similarly, established general health workers will resent being assigned what they consider as "extra" tasks. To overcome these difficulties, managers will require persistence and determination, empathy with personnel concerns, and an ability to convey an understanding of the purposes and processes of integration. In addition to training programme workers for the new tasks they are to undertake, it is important to preserve the existing career and promotion structure so that the income and future prospects of personnel are not penalized by integration.

Tuberculosis control activities at district level

It would be convenient for managers to have a standard blueprint or set of rules to follow for implementing tuberculosis control within their district, but a rigid formula obviously cannot be devised because intercountry and inter-district differences are too great. In fact, a standard "recipe" would defeat the very objective of a district health programme. All of the essential elements of primary health

care are applicable to tuberculosis control to some extent: treatment, essential drugs, disease control, immunization, mother and child health care, food and nutrition, health education, and sanitation. All are delivered by the same generalist workers, with support from higher levels. What will vary from district to district are the all-important details of how the component tasks are organized and integrated, and who assumes responsibility for each.

Consider the first objective of an integrated tuberculosis control programme, the detection and treatment of all smear-positive cases. *Case-finding* in a district occurs principally at the most peripheral level of contact, and needs to be based on one or, preferably, two sputum specimens. Where and when should the patient produce the specimens—at home or at a health post? Overnight (early morning) specimens are best because they are most likely to contain tubercle bacilli, but their collection requires prior instruction of patients and their families, who also need to be provided with a suitable container. Who should be responsible for giving the necessary instructions and supplies? Who should make the smear? Where should the smear (or the specimen) be transported and who should stain and examine it? How should the health worker and the patient be notified of the result and, if it is negative, what is the proper follow-up? If the smear is positive, exactly how, where and by whom should the patient be brought under therapy? Each of these detailed, sometimes seemingly trivial, questions must find a locally relevant answer in the district health plan.

Treatment should be so arranged that, to the greatest extent possible, drug-taking will be uninterrupted. It must therefore be as convenient to patients as possible, particularly once their presenting symptoms have been relieved and they feel well and so have less motivation to continue therapy. If the regimen includes streptomycin, the injections must be given by a health worker qualified and authorized to do so. During the initial intensive phase of therapy, drug-taking should be fully supervised, if possible by health service staff

or otherwise by a family member or senior member of the local community. Therefore, peripheral health workers from a health centre or post must give information, provide motivation, and deliver drugs to the patient, with the involvement of his or her family and the support of the local community. If there is a dependable system of community health workers, they may assume many of these responsibilities, perhaps to the extent of supervising initial-phase therapy, streptomycin apart. If so, the community health workers must keep formal records of drugs administered under supervision, and of drugs delivered at the usual one-month (or when possible shorter) interval, checking the number of tablets taken during the preceding interval. Senior members of the family or close friends may be enlisted to spur or maintain the patient's motivation. If streptomycin is included in therapy, the place where injections are given should be as close as possible to the patient's home or workplace. In a well-organized district it may be possible to arrange for patient management, especially injections and supervised therapy, to be carried out by a more convenient nearby nongovernmental health agency.

If a patient is not improving, refuses further treatment (usually a sign of drug toxicity), intends to leave or has left the community, the health worker must promptly report this to the nearest unit where appropriate action can be taken. The local health facility in the area to which the patient is moving should be notified, preferably in advance, so that treatment is not interrupted.

Supervision, including spot checking, should be provided for each level of service by the next higher level of responsibility, and should include clinical surveillance and review by staff at the district hospital. At the district health office, a file for each patient under treatment (this might be a register) should be kept and updated for general programme oversight, evaluation, and reporting to higher levels.

Stocks of essential drugs for tuberculosis chemotherapy, consistent with the regimens standard in the country, must

be kept constantly available in the “pipeline” running from the centre to the district and thence to the periphery. This requires planning based on past experience and projections of future needs, careful storage and record-keeping at all levels, and a system of accountability. If rifampicin is supplied, rigorous controls are needed to prevent its diversion and misuse; local markets should be monitored to ascertain that this drug, if available, does not originate from government supplies for treatment of tuberculosis.

Links with other programmes

Immunization of the newborn and young infants with BCG is a function of the expanded programme on immunization, which is also integrated into primary health care. Technical assessment of vaccination technique may, however, have to be organized specially.

Mother and child health is related to tuberculosis control because of the importance of childhood tuberculosis in developing countries. Children in the home of an index case are at high risk of infection and subsequent disease. Such children should be examined and treated if necessary, be given chemoprophylaxis (see section 3, page 15), or be kept under supervision, in which case their mothers need to be told about the possibility of childhood tuberculosis and instructed how to recognize the symptoms. Since diagnosis can rarely be made by sputum examination, referral of suspect children to district or higher-level hospitals is necessary. If a community health worker system is operating, these volunteers can, with the proper training and motivation, carry out many of the tasks involved.

Food and nutrition must be considered in connection with tuberculosis. No special diets are needed for patients, but poor nutrition increases susceptibility to infection as well as the risk of progression to clinical tuberculosis. Unfortunately, although health workers at the periphery can have a

direct impact on infant and young child nutrition, they can do little to raise the general level of nutrition of adults. But awareness of its importance should be included in their training, and the district health officer should collaborate in addressing the problem with the agricultural, community development, and educational sectors.

Education of the community, and of patients and their families, is an urgent necessity if the prevalence of tuberculosis is to be reduced and good patient care assured. It is needed in all aspects of tuberculosis control. People need to recognize the clinical features of the disease, to realize the value of early diagnosis and the effectiveness of treatment (combating the stigma of tuberculosis), to understand the need for close adherence to the therapeutic regimen and for the continuation of drug-taking even after the patient feels well or moves to another district, to appreciate the importance of BCG vaccination and a nutritious diet, especially for infants and children. Education about tuberculosis can be worked into every patient–health worker encounter, whatever its prime reason. Advantage should also be taken of community meetings to propagate these health messages. Health workers should be alert to special opportunities. For example, at the time a case has been diagnosed, the patient's immediate community is temporarily more receptive to education about tuberculosis.

Improvement in sanitation, with tuberculosis control in mind, means reducing household overcrowding and improving ventilation and lighting. This is a long-range development goal requiring the involvement of other governmental and nongovernmental sectors.

8. Problems encountered in the process of integration

The integration of tuberculosis control into the primary health care system is not an easy task. For convenience, the problems may be classed in two categories: conceptual and practical.

Problems with the concept of integration

Although integration is the official policy in most developing countries, the translation of policy into practice requires the commitment of the programme managers most affected. The managers of vertical tuberculosis control programmes have put forward many arguments against integration which, from a parochial perspective, may seem to have some validity and which must be countered persuasively.

- In the past, managers frequently objected that “there is nothing to integrate into”. Sometimes this was no exaggeration. But if the primary health care system is weak, the remedy is to strengthen it by reducing the competition for limited resources, among other things by reducing the size of vertical programmes.
- It has been claimed that a well-run vertical tuberculosis control programme is a good long-term investment because it will reduce the size of the problem more rapidly and help lead to eradication. This may be true in theory, but in practice no developing country can afford to fund a vertical programme heavily enough to ensure thorough countrywide coverage. Besides, it is incongruous to expend so much effort on the control of tuberculosis when equally or more pressing health problems are being neglected.

- Almost the converse of the preceding is the argument that the relatively low prevalence of tuberculosis should give it low priority in a general health care scheme. However, priority for control is governed not by prevalence alone but also by the availability of cost-effective control methods. What is true is that control of a relatively low-prevalence disease should not claim a disproportionate share of the resources.
- External support from abroad, both governmental and private, is principally attracted to clearly identified single-purpose programmes. Even when such is the case, this argument must not be permitted to determine national health care policies. Nor should it be forgotten that, in sponsored programmes, the local resources that must be used usually far exceed those provided by the donors.

Problems encountered in practice

Through their attempts at integration, or at least decentralization, a number of developing countries have succeeded in bringing tuberculosis control services within reach of the peripheral population. Unfortunately, this does not mean that communities are actually making use of the services available. Case-finding has remained almost entirely passive, often covering a mere fraction of the estimated caseload. Case-holding at the peripheral level likewise continues to be unsatisfactory; by far the best results are obtained by programmes that employ specialized staff at this level, or that carry out treatment at the referral level.

Underlying many of these problems is the unavoidable fact that the control of tuberculosis—a disease that is not often seen in any one peripheral health post—requires the repeated carrying out of a variety of tasks, especially in relation to case-finding and treatment. This means the training and re-training of large numbers of health workers at all

levels. It also means a substantial workload for peripheral personnel in searching for and managing the small number of cases they are likely to diagnose. In one country, attempts to improve case-finding through peripheral workers resulted in a doubling of the number of smears made but a halving of the proportion of positive smears. Health workers need a high level of motivation if they are to maintain efficient detection and treatment of tuberculosis cases and not turn to some other health intervention that will yield quicker, more obvious results.

The same dilemma is faced by district-level managers, for whom tuberculosis is just one of the responsibilities in their workload. Many of these workers are often burdened as well with clinical responsibilities, leaving them even less time and motivation for doing a proper managerial job. In addition to a more rational organization of clinical and managerial workloads, such personnel would benefit greatly from special training to upgrade their managerial skills.

Drugs and laboratory supplies for tuberculosis are but a small part of the overall supply needs of primary health care, and they tend to "get lost in the system". Only improvement of the general supply system will alleviate this problem.

Monitoring, surveillance and evaluation are often very weak activities in primary health care, and may have been better carried out in the vertical programme. The contrast is likely to be painful to the tuberculosis specialist. The solution is more attention to and training for these critical tasks.

It will be apparent that inadequate training and motivation is the common thread running through these problems. Training is a programme activity that is worthy of special attention. Not only is it needed for peripheral workers if they are to do their jobs well, but it is an important component of motivation and a necessary step in the integration process. An understanding of tuberculosis and of control activities should be an objective of the general training of

all peripheral workers. Refresher courses should be provided at intervals, and special attention should be given to newly recruited staff. Training of nongovernmental personnel in the health sector is vital but frequently overlooked. Private physicians, traditional healers and midwives, and pharmacists can be important adjuncts in case-finding and treatment. They should not be regarded as rivals by staff coming from a vertical tuberculosis control programme.

9. Health systems research

The practice of tuberculosis control in the context of primary health care is so new that programme managers must be constantly on the look-out for ways of overcoming the practical problems mentioned in Chapter 8. When possible, programme modifications should be based on the results of specially designed research, and not just on managerial intuition. There is an urgent need for research on many issues, particularly the training and motivation of peripheral workers and the efficacy of different chemotherapeutic regimens in field conditions.

Three types of research may be distinguished according to their objective, each applicable to a different relationship between primary health care and tuberculosis control activities.

- (a) The first type is cost-effectiveness research, aimed at optimizing the efficiency with which services are delivered, i.e., increasing or maintaining the level of service while maintaining or reducing personnel or other costs. Such research is useful wherever the health system is flexible enough to accommodate any suggested changes in service delivery.
- (b) The second type, operations research, has the aim of adapting tuberculosis control strategies to existing situations and identifying how these strategies might be best applied. This research is relevant where the primary health care structure is relatively fixed and static and tuberculosis control must be adapted to it.
- (c) The third type, interaction research, is designed to find ways of improving the functioning of both primary health care and tuberculosis control when the two are

being integrated. This type of research studies the interactions of the two systems so as to determine how both may be modified to achieve efficient integration.

Cost-effectiveness research should be within the capability of any programme manager, since it aims to optimize activities that are already in operation. Its applicability may be limited, however, to the specific primary health care programme in which it is conducted. Operations research and interaction research are more complicated, but more broadly applicable. The design of these studies should make use of the experience of investigators who have been successfully involved previously in such research.

10. External collaboration

For many years tuberculosis control programmes in developing countries have been aided by bilateral and multilateral agencies who have provided material and technical support. Prominent among these agencies have been and continue to be WHO, UNICEF and the International Union against Tuberculosis and Lung Disease (formerly the International Union against Tuberculosis), often working in close and effective collaboration. This support has always been directed to furthering integrated national tuberculosis programmes and is now aimed at tuberculosis control within primary health care. Developing countries have made effective use of this collaboration, and it should be continued and if possible expanded. In its 1982 report,¹ a Joint IUAT/WHO Study Group agreed that "fundamental changes in the world economic structure are called for and are basic for the long-term solution of health problems, emphasizing that mechanisms for increased bilateral and multilateral transfers of resources (for tuberculosis control) should be promoted". Moreover, after reviewing the financial and other benefits which have accrued to the developed world thanks to tuberculosis research carried out in developing countries, it concluded that "the technically advanced countries thus not only have an obligation to support a continuing programme of research on tuberculosis as part of the fight against the disease on a global scale, but have a direct interest in doing so".

Very often donors impose conditions or limitations on the uses to which grant funds can be put. These usually act as a

¹ WHO Technical Report Series, No. 671, 1982 (*Tuberculosis control: report of a Joint IUAT/WHO Study Group*).

stimulus to vertical programme development and result in an excessive commitment of national manpower and facilities. With the present emphasis on the building of a primary health care infrastructure, developing countries have an even greater need than before to resist the temptation to accept external assistance that does not promote, or at least complement, the development of their primary health care system.

In tuberculosis control, external support should be aimed at identified programme needs. As mentioned above, research is one such need. Training is another key component that can make the difference between success and failure; it deserves vigorous support.

A vital component of tuberculosis control—one that represents a major expense and can be expected to continue indefinitely—is the purchase of drugs. With a gradual shift to short-course regimens based on more costly drugs and better case-finding, the budget for drugs will increase. Fortunately, however, as the market for rifampicin and other expensive drugs expands, the unit price goes down. Bulk purchasing through the WHO/UNICEF Action Programme on Essential Drugs permits negotiation for even more favourable prices. Proposals for the establishment of an “international pool of essential antituberculosis drugs” have been made by various groups of tuberculosis experts. Such a pool could (a) make these drugs continuously available to developing countries unable to afford them, (b) permit agencies to contribute funds to the pool rather than to individual countries, and (c) avoid the dangers associated with donor pressure for the use of specific drugs in recipient countries. Obviously, many issues concerning the management and operation of the pool would have to be worked out in detail—for example, who would administer it, how monetary donations would be solicited and accepted, what conditions the recipient country would need to meet before receiving drugs from the pool, and how continuity of the tuberculosis control programme would be assured.

In sum, whatever the programme component being supported, external collaboration should be consonant with WHO's recommendations on tuberculosis control. It should promote the integration of tuberculosis control into primary health care and in no way disrupt or unbalance the development of the health system. Governments should avoid assistance at such a level that they become dependent on continuous external support.



Annex

WHO consultation on tuberculosis control as an integral part of primary health care

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The era of specialized health programmes, each aimed at a specific disease, is over. But while countries acknowledge the need to integrate various disease control activities into their general health services, the integration process is fraught with difficulty.

The aim of this book is to help the managers of primary health care programmes and of tuberculosis control programmes to achieve step-by-step integration, giving priority to case-finding and treatment. After a succinct presentation of what programme managers need to know about sputum smear examinations and the pros and cons of different chemotherapy regimens, the book explains how to plan and organize tuberculosis control at the all-important district level. The main managerial tasks are set out, including the proper attention to training and motivation of programme staff, many of whom may have to make the difficult transition from a specialized tuberculosis programme to primary care. Readers are alerted to the conceptual and practical problems likely to be encountered, and the usefulness of health systems research in solving these problems is stressed. The book concludes with a look at external collaboration. Bilateral and multilateral funding can do much to support tuberculosis control in the developing world, for example through an international pool of essential antituberculosis drugs, provided that countries are careful not to allow external support to distort the development of their general health systems based on primary care.